UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BEXTRA AND CELEBREX MARKETING SALES PRACTICES AND PRODUCT LIABILITY LITIGATION	)	Civil Action No. 08-mc-10008-MLW

ORDER ON PFIZER, INC.'S MOTION TO COMPEL
AND ON THE MASSACHUSETTS MEDICAL SOCIETY'S AND NEW ENGLAND JOURNAL OF MEDICINE'S MOTION FOR PROTECTIVE ORDER.

March 31, 2008

SOROKIN, M.J.

I. INTRODUCTION

Pfizer, Inc. is the defendant in a multidistrict litigation concerning its prescription arthritis medications Bextra and Celebrex pending in the United States District Court for the District of Northern California ("the MDL").[1] On May 23, 2007, Pfizer served a subpoena pursuant to Fed. R. Civ. P. 45(a)(2)(B) upon the Massachusetts Medical Society ("the MMS") and its publication, the New England Journal of Medicine ("the NEJM"), seeking documents related to articles concerning Bextra and Celebrex which appeared in NEJM, or which were considered for publication, but rejected. Docket #1-2, at 4-9. MMS and the NEJM objected on various grounds (including assertions of privilege) and the parties thereafter engaged in a protracted negotiation which narrowed, but did not resolve, the dispute. During the course of that negotiation, MMS

[1] In Re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation, Case No. 05-cv-01699-CRB, MDL No. 1699 (N.D. Ca.).

and the NEJM produced approximately 246 pages of responsive documents concerning which they had no objection. Docket #5, at ¶ 6.

On January 15, 2008, Pfizer filed its Motion to Compel (Docket #1). On January 18, 2008, the District Judge entered an Order of Reference to the undersigned. Docket #2. On January 29, 2008, MMS and the NEJM filed their Opposition and Motion for Protective Order (Docket #3, subsequently referred in Docket #16). After briefing, the motions were heard on March 13, 2008, at which time the scope of the remaining dispute was further narrowed. On the following day, MMS and the NEJM made a further submission regarding supplemental authority, and subsequently they filed a post-hearing memorandum, as did Pfizer.

II. FACTUAL AND PROCEDURAL HISTORY

The NEJM is the world's oldest and most frequently-cited medical journal. Docket #5, at ¶ 2. It publishes new medical research findings, review articles and editorial opinions on topics of interest to its more than 200,000 subscribers in biomedical science and clinical practice. Id. Physicians rely on information presented in the NEJM to follow medical developments and improve patient care. Id., at ¶ 3. Manuscripts submitted for publication by the NEJM are subject to "peer review," i.e., to screening and analysis conducted by experts in the subject matter discussed within the submitted articles. Id., at ¶ 7. Peer reviewers are given a draft manuscript and are asked to provide "a confidential, frank, honest evaluation of the manuscript's scientific validity" and to provide an overall opinion with respect to a manuscript's "worthiness for publication." Id., at ¶ 8. The peer reviewers' comments include one set intended for "editors' eyes only," and one set drafted with an understanding that they may be shared with the author. Id., at ¶ 9. Information from peer reviewers which is communicated to the authors does not

reveal the identity of the peer reviewer. Id., at ¶ 12. The NEJM informs prospective peer reviewers that it will maintain the confidentiality of their identities, unless the reviewer grants specific permission to the contrary. Id., at ¶ 13. However, nothing prevents an author (or prospective author) from sharing or disseminating the peer review comments it receives from the NEJM.

The NEJM has published at least eleven articles concerning Bextra and Celebrex and, presumably, rejected others after some measure of consideration and/or peer review. Pfizer subpoenaed from the NEJM "all documents regarding manuscripts submitted for publication to the [NEJM], whether accepted or rejected, concerning [Bextra and Celebrex]" including, but not limited to, the eleven specifically-identified articles. Docket #1-2, at 6. None of the peer reviewers for the eleven identified articles has given the NEJM permission to disclose his or her identity. Docket #5, at ¶13. The subpoena additionally sought "all documents regarding the peer review process or other assessment, analysis or evaluation of manuscripts submitted for publication," whether or not they had been accepted for publication, and again delineating the same eleven specific articles. Docket #1-2, at 7-8. Pfizer further sought the peer review comments as well as documents identifying the peer reviewers, for any other articles (accepted or rejected) concerning Bextra and Celebrex. Id., at 8.

Pfizer seeks these documents to assist with its defense in an MDL in which products liability Plaintiffs allege that Pfizer's Bextra and Celebrex caused cardiovascular and other injuries. See Docket #1 at 2. The published articles, Pfizer asserts, "are being used against Pfizer" in the MDL, via allegations that Pfizer failed to act upon the results of studies described in the scientific literature, and that it was on notice thereby of the alleged risks presented by Bextra and Celebrex.

Docket #1, at ¶ 5 citing Exhibit B thereto. Pfizer asserts that the documents it seeks would explain why certain data was published (or not) and the reason articles may emphasize particular issues.[2] Docket #15, at 3. Pfizer's papers make plain that it requests the documents to identify "'flaws in methodology'" in the published articles. Docket # 1, at 9 (quoting Lofgren v. Motorola, 1998 WL 299925 at *7-8 (Ariz. Super. June 1, 1998)). Thus, Pfizer contends that all of the subpoenaed documents are relevant to the MDL.

During the course of the negotiations between the parties, the NEJM produced general communications between their editors and the authors of articles related to Bextra and Celebrex, but withheld any communications (or at least the portions thereof) containing peer reviewer comments or editorial comments, as well as the so called "peer review sheets," which include comments intended to be shared with the authors. See Docket #14-2, at n. 1.

At the March 13, 2008, hearing, Pfizer substantially narrowed the scope of its Motion to Compel. Specifically, Pfizer informed the court that it sought only (1) the complete record of communications between the NEJM editors and the authors of any articles (published or unpublished) concerning Celebrex or Bextra and (2) copies of any documents produced, voluntarily or otherwise, in connection with any dispute concerning Celebrex or Bextra. Thus, Pfizer withdrew its requests seeking documents reflecting the peer reviewer comments which were not shared with the authors, internal editorial comments or processes, or the identities of the peer reviewers (something Pfizer had disclaimed in its original motion as well). The Defendants

[2] The plaintiffs also accuse Pfizer of "failing to publish study results, of publishing only partial study results, and of publishing study results too late," Docket # 1 at ¶5. However, Pfizer has not laid any basis to establish that it requires documents from the NEJM to address these claims, e.g. in order to show that it attempted to publish a study but that the NEJM thwarted the efforts by rejecting the proposed article.

represented that they possessed no documents responsive to the second request (i.e., that they had not produced documents in connection with any dispute concerning Celebrex or Bextra). Only one issue for decision remains: whether Pfizer may compel the Defendants to produce the substance of their communications with the authors of articles concerning Celebrex or Bextra.

III. DISCUSSION

Fed. R. Civ. P. 26(b)(2)(c) provides in relevant part that "[o]n motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that: (i) the discovery sought . . . can be obtained from some other source that is more convenient, less burdensome, or less expensive . . . [or] (iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues." Fed. R. Civ. P. 26(b)(2)(c). This provision initially governs enforcement of a Rule 45 subpoena.

The First Circuit has established that in the course of conducting the balancing test articulated in Rule 26(b)(2)(c)(iii), the Court must consider whether the materials possessed by the NEJM and MMS comprise confidential information entitled to special consideration and then must determine "the type and kind of protection" afforded to them. Cusumano v. Microsoft Corp., 162 F.3d 708, 714 (1st Cir.1998).[3] The party who has served a subpoena seeking pre-

[3] In their written submissions, the MMS and the NEJM also raised as bars to the discovery of the materials certain privileges, none of which were pressed with particular vigor at the March 13, 2008, hearing (except to the extent that the Rule 26 balancing test articulated above is informed by First Amendment principles). The Court finds that the privileges cited (e.g., a reporter's privilege, a peer review privilege, and the First Amendment privilege) are not directly applicable, except to the extent that they are factors in the balancing test here described. The First Circuit has cautioned against engaging in semantic discussions about whether or not the

publication information compiled by an academic researcher must first make a prima facie showing that its "claim of need and relevance is not frivolous." Id., at 716. The objector must then demonstrate its basis for withholding the information, and the Court must balance "the movant's need for the information on one pan of the scales and . . . the objector's interest in confidentiality and the potential injury to the free flow of information that disclosure portends on the opposite pan." Id., citing Bruno & Stillman, Inc. v. Globe Newspaper Co., 633 F.2d 583, 597-598 (1st Cir.1980). Finally, "a factor entitled to special weight" in conducting this balancing test is that MMS and the NEJM are non-party strangers to the MDL. Cusumano, 162 F.3d at 717.

A. More Convenient, Less Burdensome Or Less Expensive Sources Are Unavailable

At the March 13th hearing, Pfizer's counsel indicated that it had received some of the materials it seeks directly from those authors whom it has deposed. Although the authors, according to the NEJM, are free to disclose the communications that Pfizer seeks from the NEJM, nevertheless, the authors are not a more convenient, less burdensome or less expensive source within the meaning of the Rule. Pfizer would have to expend substantially more effort to obtain the documents piecemeal from each author than directly from the NEJM. In addition, regarding the unpublished articles, Pfizer has no way of obtaining the documents as it does not know the identity of the authors.

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protection to be afforded to information compiled pre-publication by an academic researcher constitutes a "privilege," instead laying out the analytical framework here described.

B. The Materials Sought By Pfizer Are Relevant To The MDL, But Of Limited Probative Value

The first step in determining whether "the burden or expense of the proposed discovery outweighs its likely benefit" within the meaning of Rule 26(b)(2)(c)(iii) is to assess the relevance and probative value in the MDL of the materials Pfizer seeks. Pfizer points out that certain studies published in the NEJM are central to the MDL Plaintiffs' theory of liability because the Plaintiffs have argued that publication of those articles, inter alia, put Pfizer on notice of the cardiovascular risks of Bextra and Celebrex, and that the authors of the articles are expected to testify at trial. See, e.g., Docket #1, at ¶ 5.

Thus, the materials are within the scope of discovery generally permitted by Rule 26 (b)(1) (i.e., they are information that is "relevant to any party's claim or defense" and "reasonably calculated to lead to the discovery of admissible evidence") because the materials are likely to contain comments from the peer reviewers which could form a basis for impeachment of the authors. Although the materials are relevant, their probative value is nevertheless limited. See Cusumano, 162 F.3d at 712 (affirming denial of motion to compel where documents primary use was for impeachment type purposes); Plough, Inc. v. Nat'l Academy of Sciences, 530A.2d 1152, 1160 (D.C.1987) (finding impeachment use to rebut non-party Academy's prestige is "attenuated kind of 'necessity'" at best). The Plaintiffs' claims focus on what Pfizer knew, or should have known, via published articles in the scholarly literature. The peer reviewers' confidential comments – which Pfizer even now has yet to discover – hardly speak to that issue. Moreover, Pfizer's own experts are equally able to review and analyze the articles for flaws in methodology or otherwise. For example, as Pfizer explains, "Pfizer is interested in the content only so that it

may present the totality of the scientific data to the juries in its product liability cases and so that Pfizer may explain that reasonable scientific minds frequently differ over complicated pharmacological and biomechanical issues." Docket #7, at 3. The peer reviewer comments contain no "data" though, and Pfizer has available to it both its own experts as well as any publicly-available research or commentary regarding the published articles or Celebrex and Bextra.

Pfizer also wishes to use the materials to impeach any causation experts offered by the Plaintiffs, or alternatively to provide ammunition for their own causation experts (and, as conceded at the hearing, to do so with the significant imprimatur of the NEJM added to that ammunition). See, e.g., Docket #1, at ¶¶ 6-7. The NEJM has rightly characterized this effort as "coopting the expertise of the NEJM and its outside reviewers" in lieu of [or, more likely, in addition to] hiring its own experts to attack the Plaintiffs' causation theories. Docket # 4, at 13. Moreover, this Court may quash or modify a subpoena seeking materials that "does not describe specific occurrences in dispute and results from [an] expert's study that was not requested by a party." Fed. R. Civ. P. 45(c)(3)(B)(ii). The 1991 amendment notes to Rule 45 indicate that Rule 45(c)(3)(B)(ii) provides "appropriate protection for the intellectual property of the non-party witness. . . . A growing problem has been the use of subpoenas to compel the giving of evidence and information by unretained experts." See Fed. R. Civ. P. 45 advisory committee's note (1991 Amendment, Subdivision (c)(3)(B)(ii)). The peer reviewers' comments do not address the appropriateness, or lack thereof, of Pfizer's response to the publication of any NEJM articles, nor were those comments created at the request of a party to the MDL. The Court therefore concludes that to the extent Pfizer seeks the materials for these purposes, the NEJM is entitled to

protection afforded by Rule 45(c)(3)(B)(ii), and in any event, the subpoenaed documents have limited probative weight under the circumstances.

C. The MMS and the NEJM Are Entitled to A Level Of Protection Commensurate With That Afforded Journalists.

The Cusumano case concerned materials related to interviews of Netscape employees compiled for an as-yet unpublished book about the so-called "browser wars" between Netscape and Microsoft. Cusumano, 162 F.3d at 711. The First Circuit considered therein the proper level of protection to be afforded to academics engaged in pre-publication research, and concluded that the same concerns which motivate the protection of journalistic endeavors (i.e., the avoidance of a chilling effect on the ability of the press to gather and disseminate information) also justify providing protection to academics engaged in scholarly research. Id, at 714. The First Circuit first noted the protection from discovery afford to journalists in order to avoid undermining their ability to gather and disseminate information. Id. citing United States v. LaRouche Campaign, 841 F.2d 1176, 1181 (1st Cir.1988). The Court reasoned that like journalists, scholars are "information gatherers and disseminators," and a consideration central to the Cusumano result was the fact that the researchers in question intended to compile and analyze the information they had collected from their industry sources for dissemination to the wider internet technology industry. Id., at 714-715.

The uncontradicted submissions from the NEJM place this case comfortably within the ambit of Cusumano. The NEJM emphasizes that the peer review process (as described supra at pp. 3-4) "contributes to the advancement of medicine and science by helping to ensure that faulty, incomplete, or misleading results are not published." Docket #5, at ¶ 11. It asserts that without

the participation of its unpaid peer reviewers, "the NEJM's ability to advance medical knowledge would be severely impaired, resulting in adverse consequences for physicians, patient care, and for society as a whole." Id. It maintains that the confidentiality of the peer reviewers permits the reviewers to "be as frank as possible in their assessments of submitted science" and that if reviewers thought their names or reviews would be subject to disclosure in unrelated litigation, there would be "chilling effect" on the peer review process and as a result, upon the medical community. Id., at ¶¶ 13-14. It believes that its ability to attract peer reviewers would be impaired by disclosure of their identities or comments. Id., at ¶ 22. It further states that disclosure of the comments themselves, even without identifying the peer reviewer by name, may well disclose the reviewer's identity because in the small scientific community, an opinion may constitute a recognizable "intellectual signature." Id., at ¶ 15. Finally, it suggests that reviewers lacking confidentiality might face retaliation from those authors whom they have criticized. Id., at ¶ 16.

The foregoing factual submissions are not only uncontradicted, but persuasive. The NEJM disseminates medical information not only from its authors, but also from its peer reviewer sources in the medical field, who help to ensure that the articles disseminated to the medical and scientific communities are of the highest quality. Even the more limited NEJM materials now at issue (the NEJM's communications with authors) are of a more-clearly confidential nature than those that were at issue in the Cusumano case, which the First Circuit found to be "along the continuum of confidentiality at a point sufficient to justify significant protection."[4] Cusumano,

[4] In Cusumano, much of the material collected was eventually to be made public in the published book. Cusumano, 162 F.3d at 715, n. 4. The record was also "murky" as to whether the interviewees had received assurances of their ability to prevent publication of a comment upon

162 F.3d at 715. Also, these comments are both part of scholarly research efforts as well as part of the editorial process of a print publication. Indeed the publisher of the NEJM confirms that the peer review comments are "part of the editorial process of working an article into final, publishable form." Docket 14-3, at ¶ 5. "Courts afford journalists a measure of protection from discovery initiatives" and afford "a similar level of protection for . . . academic researchers." Cusumano, 162 F.3d at 714. The batch or wholesale disclosure by the NEJM of the peer reviewer comments communicated to authors will be harmful to the NEJM's ability to fulfill both its journalistic and scholarly missions, and by extension harmful to the medical and scientific communities, and to the public interest.[5]

Recently the Northern District of Illinois declined to compel compliance with identical (or virtually identical) subpoenas served by Pfizer in this MDL on the Journal of the American Medical Association and the Archives of Internal Medicine. Docket #13-2, In re Bextra and Celebrex, C.A. No. 08C 402 (N.D.Ill. March 14, 2008) (Keys, M.J.). The Court found that the "information kept confidential from Pfizer, the general public and the medical community at large,

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their objection. There is no such ambiguity regarding the NEJM's assurances of confidentiality to its peer reviewers. See Docket #5, at ¶ 13. That the NEJM imposes no legal restriction on the author limiting the author's disclosure of the peer review comments shared with him or her does not change the analysis in this case. The record before the Court establishes that the communications are treated as confidential notwithstanding the absence of a legal prohibition on disclosures. Moreover, the First Circuit has "noted [without definitively deciding], in a situation involving only nonconfidential information, 'a lurking and subtle threat to journalists and their employers if disclosure of outtakes, notes, and other unused information, even if nonconfidential, becomes routine and casually, if not cavalierly compelled.'" Cusumano, 162 F.3d at 715 (quoting United States v. LaRouche, 841 F.2d 1182 (1st Cir.1988)).

[5]The wholesale disclosure of the communications will have an adverse effect even though Pfizer can, and has, obtained some communications in the course of its depositions of individual authors.

is irrelevant to" the MDL claims, id. at 5, that "any probative value would be outweighed by the burden imposed on the Journals in invading the sanctity" of the peer review process, id. at 7, and that "it is not unreasonable to believe that compelling production of peer review documents would compromise the process," id. at 8. Thus, the Court found "that whatever probative value the subpoenaed documents and information may have is outweighed by the burden and harm that would result if the Journals are forced to comply with those subpoenas." Id. at 12; see also Plough, 530 A.2d at 1160 (rejecting drug manufacturer's claim to internal NAS documents where manufacturer can "rebut the conclusions of the [NAS] Study and . . . NAS's evaluation of that Study . . .by having its own experts testify" and NAS is a non-party). The Northern District's reasoning and analysis applies with equal force to the documents sought by Pfizer in this matter.

IV. CONCLUSION

Pfizer has made a prima facie showing of relevance, although the probative value of the evidence is limited. On the other hand, the NEJM's interest in maintaining the confidentiality of the peer review process is a very significant one, especially in light of its non-party status, and tips the scales in favor of the NEJM. Accordingly, Pfizer's Motion to Compel (Docket #1) is DENIED. MMS' and the NEJM's Motion For Protective Order (Docket #3) is ALLOWED.

SO ORDERED.

/s / Leo T. Sorokin
UNITED STATES MAGISTRATE JUDGE

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1:08-mc-10008-MLW In Re: Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation
Mark L. Wolf, presiding
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